DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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May 3, 1999

Nancy L. Buc, Esq.
Buc & Beardsley
919 Eighteenth Street, N.W.
Suite 600
Washington, D.C. 20006-5503

Dear Ms. Buc:

I am responding to your letter of March 15, 1999, addressed to the Dockets Management Branch (Levothyroxine Sodium Docket No. 97N-0314). Your letter expresses concern that a statement contained in a letter from the Division of Drug Marketing, Advertising, and Communications (DDMAC) to Nancy Cafmeyer dated February 1, 1999, may indicate that the FDA has prejudged the issue of whether Synthroid is generally recognized as safe and effective. The statement in the DDMAC letter is: "Levothyroxine drug products, such as Levoxyl and Synthroid, are not generally recognized as safe and effective and are not currently recognized by FDA as bioequivalent."

FDA's August 14, 1997, Federal Register notice on levothyroxine stated: "[N]o currently marketed orally administered levothyroxine sodium product has been shown to demonstrate consistent potency and stability and, thus, no currently marketed orally administered levothyroxine sodium product is generally recognized as safe and effective." The statement in the DDMAC letter is simply a restatement of the Federal Register notice. I assure you that the agency has not prejudged the issues raised in Knoll's December 15, 1997 citizen petition and intends to give them full and fair consideration.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy

97N-0314

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